

WHAT IS CLAIMED:

- 1 1. A method for treating an autoimmune disease in a
2 mammal, the method comprising administering to said mammal an
3 effective amount for treating said disease of a bystander
4 antigen, said antigen eliciting the release of transforming
5 growth factor beta (TGF- β) at a locus within the body of said
6 mammal wherein T cells contributing to autoimmune response are
7 found to suppress the T-cells contributing to said response.
- 1 2. The method of claim 1 wherein said bystander
2 antigen is specific to an organ or tissue afflicted by immune
3 attack during said disease.
- 1 3. The method of claim 2 wherein said bystander
2 antigen is not an autoantigen.
- 1 4. The method of claim 2 wherein said bystander
2 antigen is an autoantigen.
- 1 5. The method of claim 2 wherein said bystander
2 antigen comprises a portion of an autoantigen but excludes at
3 least one epitope of said autoantigen that is recognized by
4 immune system cells contributing to said disease.
- 1 6. The method of claim 1 wherein said bystander is
2 administered to said mammal via oral route.
- 1 7. The method of claim 1 wherein said bystander is
2 administered to said mammal via inhalation.
- 1 8. The method of claim 1 wherein:
2 said bystander antigen is administered by oral
3 route or by inhalation;
4 said oral or inhalable bystander antigen elicits
5 suppressor T-cells that cause the release of TGF- β ;

6 said bystander antigen is not specific to an
7 organ or tissue afflicted by immune attack during said disease;
8 said method further comprising also:
9 administering to said mammal the same bystander antigen via
10 parenteral route, thereby causing said suppressor T-cells to be
11 targeted to the same loci within the body of said mammal
12 wherein the cells contributing to autoimmune attack are found.

1 9. The method of claim 1 wherein said disease is
2 selected from the group of multiple sclerosis and animal models
3 therefor, and said bystander antigen is selected from the group
4 of myelin basic protein, proteolipid protein, fragments thereof
5 comprising at least one suppressive epitope, and combinations
6 of any two of the foregoing.

1 10. The method of claim 9 wherein said bystander
2 antigen comprises MBP peptide 21-40.

1 11. The method of claim 1 wherein said disease is
2 selected from the group consisting of rheumatoid arthritis and
3 animal models therefor and said bystander antigen is selected
4 from the group consisting of Type I collagen, Type II collagen,
5 fragments thereof comprising a suppressive epitope and
6 combinations of two or more of the foregoing.

1 12. The method of claim 1 wherein said disease is
2 selected from the group consisting of Type I diabetes and
3 animal models therefor and said bystander antigen is selected
4 from the group consisting of glucagon, insulin, fragments
5 thereof comprising at least one suppressive epitope, and
6 combinations of two or more of the foregoing.

1 13. The method of claim 1 wherein said disease is
2 selected from the group consisting of uveoretinitis and animal
3 models therefor and said bystander antigen is selected from the

4 group consisting of S-antigen, interphotoreceptor retinoid
5 binding protein (IRBP), fragments thereof comprising at least
6 one suppressive epitope, and combinations of two or more of the
7 foregoing.

1 14. The method of claim 1 further comprising
2 administering to said mammal an amount of a synergist effective
3 in combination with said bystander antigen to treat said
4 disease.

1 15. A pharmaceutical oral dosage form for treating
2 an autoimmune disease in a mammal, the form comprising:
3 an effective amount for treating said disease of
4 a bystander antigen, said antigen upon administration eliciting
5 the release of transforming growth factor beta (TGF- β) at a
6 locus within the body of said mammal wherein T cells
7 contributing to autoimmune response are found to suppress the
8 T-cells contributing to said response; and
9 a pharmaceutically acceptable carrier or
10 diluent.

1 16. The oral dosage form of claim 15 wherein said
2 bystander antigen is specific to an organ or tissue afflicted
3 by immune attack during said disease.

1 17. The oral dosage form of claim 16 wherein said
2 bystander antigen is not an autoantigen.

1 18. The oral dosage form of claim 16 wherein said
2 bystander antigen is an autoantigen.

1 19. The oral dosage form of claim 16 wherein said
2 bystander antigen comprises a portion of an autoantigen
3 comprising an immunosuppressive epitope but excludes at least

4 one epitope of said autoantigen that is recognized by immune
5 system cells contributing to said disease.

1 20. The oral dosage form of claim 15 wherein said
2 disease is selected from the group of multiple sclerosis and
3 animal models therefor, and said bystander antigen is selected
4 from the group of myelin basic protein, proteolipid protein,
5 fragments thereof comprising at least one suppressive epitope,
6 and combinations of any two of the foregoing.

1 21. The oral dosage form of claim 20 wherein said
2 bystander antigen comprises MBP peptide 21-40.

1 22. The oral dosage form of claim 15 wherein said
2 disease is selected from the group consisting of rheumatoid
3 arthritis and animal models therefor and said bystander antigen
4 is selected from the group consisting of Type I collagen, Type
5 II collagen, fragments thereof comprising a suppressive epitope
6 and combinations of two or more of the foregoing.

1 23. The oral dosage form of claim 15 wherein said
2 disease is selected from the group consisting of Type I
3 diabetes and animal models therefor and said bystander antigen
4 is selected from the group consisting of glucagon, insulin,
5 fragments thereof comprising at least one suppressive epitope,
6 and combinations of two or more of the foregoing.

1 24. The oral dosage form of claim 15 wherein said
2 disease is selected from the group consisting of uveoretinitis
3 and animal models therefor and said bystander antigen is
4 selected from the group consisting of S-antigen,
5 interphotoreceptor retinoid binding protein (IRBP), fragments
6 thereof comprising at least one suppressive epitope, and
7 combinations of two or more of the foregoing.

1 25. The oral dosage form of claim 15 further
2 comprising administering to said mammal an amount of a
3 synergist effective in combination with said bystander antigen
4 to treat said disease.

1 26. A pharmaceutical inhalable dosage form for
2 treating an autoimmune disease in a mammal, the form
3 comprising:
4 an effective amount for treating said disease of
5 a bystander antigen, said antigen upon administration eliciting
6 the release of transforming growth factor beta (TGF- β) at a
7 locus within the body of said mammal wherein T cells
8 contributing to autoimmune response are found to suppress the
9 T-cells contributing to said response; and
10 a pharmaceutically acceptable carrier or
11 diluent.

1 27. The inhalable dosage form of claim 26 wherein
2 said bystander antigen is specific to an organ or tissue
3 afflicted by immune attack during said disease.

1 28. The inhalable dosage form of claim 26 wherein
2 said bystander antigen is not an autoantigen.

1 29. The inhalable dosage form of claim 26 wherein
2 said bystander antigen is an autoantigen.

1 30. The inhalable dosage form of claim 26 wherein
2 said bystander antigen comprises a portion of an autoantigen
3 comprising an immunosuppressive epitope but excludes at least
4 one epitope of said autoantigen that is recognized by immune
5 system cells contributing to said disease.

1 31. The inhalable dosage form of claim 26 wherein
2 said disease is selected from the group of multiple sclerosis

3 and animal models therefor, and said bystander antigen is
4 selected from the group of myelin basic protein, proteolipid
5 protein, fragments thereof comprising at least one suppressive
6 epitope, and combinations of any two of the foregoing.

1 32. The inhalable dosage form of claim 31 wherein
2 said bystander antigen comprises MBP peptide 21-40.

1 33. The inhalable dosage form of claim 26 wherein
2 said disease is selected from the group consisting of
3 rheumatoid arthritis and animal models therefor and said
4 bystander antigen is selected from the group consisting of Type
5 I collagen, Type II collagen, fragments thereof comprising a
6 suppressive epitope and combinations of two or more of the
7 foregoing.

1 34. The inhalable dosage form of claim 26 wherein
2 said disease is selected from the group consisting of Type I
3 diabetes and animal models therefor and said bystander antigen
4 is selected from the group consisting of glucagon, insulin,
5 fragments thereof comprising at least one suppressive epitope,
6 and combinations of two or more of the foregoing.

1 35. The inhalable dosage form of claim 26 wherein
2 said disease is selected from the group consisting of
3 uveoretinitis and animal models therefor and said bystander
4 antigen is selected from the group consisting of S-antigen,
5 interphotoreceptor retinoid binding protein (IRBP), fragments
6 thereof comprising at least one suppressive epitope, and
7 combinations of two or more of the foregoing.

1 36. The inhalable dosage form of claim 26 further
2 comprising administering to said mammal an amount of a
3 synergist effective in combination with said bystander antigen
4 to treat said disease.

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